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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/975,530 | 10/10/2001 | Jon G. Wilkes | 4239-60896 | 9402 |

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EXAMINER

LY, CHEYNE D

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,530

Applicant(s)

WILKES ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The art unit designated for this application has changed. Applicants(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-19, drawn to a method for identifying a microorganism that is metabolically similar to a microorganism of interest, classified in class 435, subclass 29. If this Group is elected, then the below summarized 3 species sets (Environmental condition parameter, Fingerprint Spectra and Microorganisms), election of a species from each set is required.
 - II. Claims 20-32, drawn to a method for compensating drift in fingerprint spectra due to changes in environmental factors, classified in class 435, subclass 29. If this Group is elected, then the below summarized 3 species sets (Environmental condition parameter, Fingerprint Spectra and Microorganisms), election of a species from each set is required.
 - III. Claims 33-38, drawn to a method for identifying a microorganism of interest, comprising culturing on a test growth medium a microorganism of interest, classified in class 435, subclass 29. If this Group is elected, then the below summarized 3 species sets (Environmental condition parameter, Fingerprint Spectra and Microorganisms), election of a species from each set is required.
 - IV. Claims 39-47, drawn to a method for identifying an unknown microorganism, classified in class 435, subclass 29. If this Group is elected, then the below

summarized 3 species sets (Environmental condition parameter, Fingerprint Spectra and Microorganisms), election of a species from each set is required.

- V. Claims 48-58, drawn to a method of assembling a library database of fingerprint spectra for microbial identification, classified in class 702, subclass 19. If this Group is elected, then the below summarized 3 species sets (Environmental condition parameter, Fingerprint Spectra and Microorganisms), election of a species from each set is required.
- VI. Claims 59-61, drawn to a method of consulting a database of fingerprint spectra of microorganism cultured on a library database medium to identify an unknown microorganism, classified in class 702, subclass 19. If this Group is elected, then the below summarized 3 species sets (Environmental condition parameter, Fingerprint Spectra and Microorganisms), election of a species from each set is required.
- VII. Claims 62-66, drawn to a method for identifying a microorganism of interest, classified in class 435, subclass 29. If this Group is elected, then the below summarized 3 species sets (Environmental condition parameter, Fingerprint Spectra and Microorganisms), election of a species from each set is required.

SPECIE ELECTION REQUIREMENT FOR GROUP I-VII:

- 3. This application contains claims directed to the following patentably distinct species of the claimed invention:
- 4. Species of environmental condition parameter are cited in claims 4 and 31, which are generally separately analyzed and published, and thus document the undue search burden if

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searched together. Thus, applicants are required to select a type of environmental condition parameter from those listed in claims 4 and 31.

5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims in Groups I-VII are generic. These species are distinct due to being physical properties that are generally individually determined. Therefore, the different properties each species cause the species to be distinct.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

SPECIE ELECTION REQUIREMENT FOR GROUP I-VII:

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2. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species of fingerprint spectra are cited in claims 8, 22, 36 and 47, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to select a type of fingerprint spectra from those listed in claims 8, 22, 36 and 47. It is noted that these fingerprint spectra types are utilized in all Groups although only cited specifically in Groups I, II, III and IV.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the claims in Groups I-VII are generic to the above species of fingerprint spectra in Group 8, 22, 36 and 47.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

SPECIE ELECTION REQUIREMENT FOR GROUP I-VII:

9. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species of bacterial pathogen and metabolically similar organisms are cited in claim 45 and others not specified in claim 45, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to select a type of microorganism from those cited in claim 45 and thereof. It is noted that these microorganism types are utilized in all Groups although only cited specifically in Group IV.

10. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-44 and 46-66 are generic to the species of microorganisms listed above.

11. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

13. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. The inventions of Groups I-VII are distinct inventions because they are directed to different methods regarding the critical limitations and active steps therein. For Group I, the critical limitation is a method for identifying a microorganism that is metabolically similar to a microorganism of interest. For Group II, the critical limitation is a method for compensating drift in fingerprint spectra due to changes in environmental factors. For Group III, the critical limitation is a method for identifying a microorganism of interest comprising culturing on a test medium. For Group IV, the critical limitation is a method for identifying an unknown microorganism. For Group V, the critical limitation is a method of assembling a library database of fingerprint spectra for microbial identification. For Group VI, the critical limitation is a method of consulting a database of fingerprint spectra of microorganism cultured on a library database medium to identify an unknown microorganism. For Group VII, the critical limitation is a method for identifying a microorganism of interest. It is acknowledged that the commonality for the inventions above is the microorganisms and related data, however, the completely distinct intended goal and supporting active step of each method cause these inventions to be distinct.

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Therefore, the Group of inventions listed above support the undue search burden if they were examined together. Additionally, these methods have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being search separately.

15. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

16. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

18.

19. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

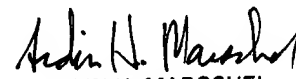
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20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

22. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
2/24/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER